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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,827	01/08/2002	John G. Keimel	P-9590.00	2655

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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,827	KEIMEL, JOHN G.	
	Examiner	Art Unit	
	Navin Natnithithadha	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-24* is/are rejected.

7)☒ Claim(s) *8,9 and 25-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings are objected to because:

a) The drawings appear to be Xeroxed copies and have ink marks bled through onto the drawings; and

b) Figure 1 shows the use of label 18 on two different structures (see page 3, lines 29-30).

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:

On page 7, line 23, it appears "conductor 254" should be

-- conductor 154 -- (see figure 4A).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 13 recites the limitation "one or more activated sensors" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears claim 13 should be dependent on claim 12 and not claim 10 because the antecedent basis for the limitation "one or more activated sensors" is in claim 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Kaplan, U.S. Patent No. 6,331,163 B1.

In regards to claim 1, Kaplan discloses a sensor system (see figure 15), comprising: a sensor 30 to sense a biological indicator; and a protective member (protective layer) 150 located adjacent to the sensor to shield the sensor from a surrounding environment for a selectable time period (see column 15, lines 30-65).

As to claim 5, Kaplan discloses a material that substantially dissolves within a living body (see column 15, lines 41-43).

6. Claims 1, 5, and 11, are rejected under 35 U.S.C. 102(b) as being anticipated by Koning et al, U.S. Patent No. 4,534,825 B1.

In regards to claim 1, Koning et al discloses a sensor system (see figure 7), comprising: a sensor 51 to sense a biological indicator; and a protective member (protective layer) 53 located adjacent to the sensor to shield the sensor from a surrounding environment for a selectable time period (see column 4, lines 1-14).

As to claim 5, Kaplan discloses a material that substantially dissolves within a living body (see column 4, lines 1-14).

In regards to claim 11, Koning et al discloses a system for sensing a biological agent (see figure 7), comprising: at least two sensors 51 and 52; and a protective member (layer) 53 covering both the sensors to prevent the sensors from interacting with a surrounding environment (see column 4, lines 1-14).

7. Claims 1-3, 5-7, 9, 10-13, and 19-24, are rejected under 35 U.S.C. 102(b) as being anticipated by Marks et al, U.S. Patent No. 6,203,758 B1.

In regards to claim 1, Marks et al discloses a sensor system (see figures 2 and 3), comprising: a sensor (micro-electrode) 18 to sense a biological indicator; and a protective member (protective layer) 24 located adjacent to the sensor to

shield the sensor from a surrounding environment for a selectable time period (see column 11, line 56, to column 12, line 42).

As to claim 2, Marks et al discloses a control circuit coupled to the protected member to disable (deprotect) the protective member after the selectable time period (see column 12, lines 26-36).

As to claim 3, Marks et al discloses a protective member 24 formed of biocompatible metal, i.e. copper (see column 12, lines 15-25).

As to claim 5, Marks et al discloses a protective member 24 formed of a material (copper) that substantially dissolves (undergoes a chemical reaction) within a living body over the selectable time period (see column 12, lines 4-25).

As to claim 6, Marks et al discloses using a chemical reaction to deprotect the sensor 18 when electronically activated (see column 12, lines 15-36).

As to claim 7, Marks et al discloses including multiple sensors 18, each associated with a protective member 24, and wherein the control circuit includes a circuit capable of selectively disabling one or more of the protective members (see column 12, lines 26-36).

As to claim 10, Marks et al discloses the sensor 18 for performing analyses of multimolecular interactions in assays for human physiological fluids (see column 1, lines 6-28).

In regards to claim 11, Marks et al discloses a system for sensing a biological agent (see figures 2 and 3), comprising: at least two sensors 18; and a

protective member (layer) 24 covering both the sensors to prevent the sensors from interacting with a surrounding environment (see column 11, lines 56-64).

As to claim 12, Marks et al discloses a control circuit to disable one or more selected ones of the at least two protective members 24, whereby one or more respective sensors are activated to interact with the surrounding environment (see column 12, lines 26-36).

As to claim 13, Marks et al discloses a processing circuit 92 (see figure 14).

In regards to claim 19, Marks et al discloses a method of sensing signals in a living body (see Abstract), comprising: providing a sensor 18 (see column 11, lines 56-60; providing a protective member 24 to prevent the sensor from interacting with the living body (see column 11, lines 56-64); selectively disabling the protective member (see column 12, lines 26-36); and obtaining at least one signal (see column 19, lines 11-19).

As to claim 20, Marks et al discloses using a chemical reaction to deprotect the sensor 18 when electronically activated (see column 12, lines 15-36).

As to claim 21, Marks et al discloses providing a protective member 24 that is dissolvable within the living body within a predetermined period of time, and exposing the protective member to the living body (see column 11, line 65, to column 12, line 25).

As to claim 22, Marks et al discloses providing multiple sensors 18, providing multiple protective members 24 (see column 11, lines 56-64); and disabling at least one of the multiple protective members 24 to activate a selected one or more of the multiple sensors (see column 12, lines 26-36).

As to claims 23 and 24, Marks et al discloses obtaining multiple signals from activated ones of the multiple sensors and processing the multiple signals (see column 19, lines 11-19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Marks et al, U.S. 6,203,758 B1.

Marks et al discloses claims 1 and 2 as discussed above.

As to claim 4, Marks et al does not specifically disclose the protective member 24 is formed of erodible polymer gel. However, he does disclose the protective member 24 is formed of copper. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Marks et al protective member 24 to be formed of an erodible polymer gel because he suggest or provides motivation for use of other materials as the protective

member 24 in column 12, lines 4-14, where he states that "other types of chemical reactions could be suitable for deprotection of the micro-electrode [18], depending upon the type of protective layer...".

Allowable Subject Matter

9. Claims 8-9, 14-18, and 25-30, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

As to claims 8 and 9, the prior art does not disclose the claimed invention of claim 7, and including a processing circuit to determine when operation of any of the multiple sensors is degrading.

As to claim 14, the prior art does not disclose the claimed invention of claim 13, and including the processing circuit includes means to discard one or more sensor signals prior to processing the remaining sensor signals.

As to claims 15-17, the prior art does not disclose the claimed invention of claim 13, and including a therapy delivery system coupled to the control circuit.

As to claim 18, the prior art does not disclose the claimed invention of claim 13, and including a circuit to obtain the sensor signals in a time-multiplexed manner.

As to claim 25, the prior art does not disclose the claimed invention of claim 24, and including discarding selected ones of the multiple signals that are determined to be outside of a pre-defined signal range.

As to claims 26 and 27, the prior art does not disclose the claimed invention of claim 24, and including determining that one or more of the multiple sensors are becoming degraded based on the multiple signals.

As to claim 28, the prior art does not disclose the claimed invention of claim 24, and including obtaining the multiple signals includes receiving signals from the activated ones of the multiple sensors in a time-multiplexed manner.

As to claims 29 and 30, the prior art does not disclose the claimed invention of claim 19, and including providing therapy to the living body based on at least one signal

11. Claims 13-18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (703) 305-2445. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Navin Natnithithadha
Patent Examiner
GAU 3736
February 28, 2003